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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,106

09/10/2007

Judith A. Fox

GC822-US

5374

5100

7590

12/21/2011

DANISCO US INC.

ATTENTION: LEGAL DEPARTMENT

925 PAGE MILL ROAD

PALO ALTO, CA 94304

EXAMINER

DENT, ALANA HARRIS

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

12/21/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,106	Applicant(s) FOX ET AL.	
	Examiner Alana Harris Dent, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-28 is/are pending in the application.
- 5a) Of the above claim(s) 15-28 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-14 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-14) in the reply filed on October 28, 2011 is acknowledged.

2. Claims 1-28 are pending.

Claims 15-28, drawn to non-elected inventions are withdrawn from examination.

Claims 1-14 are examined on the merits.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-14, as written, do not sufficiently distinguish over antibodies as they exists naturally because these claims do not particularly point out any non-naturally occurring differences between the claimed antibodies thereof and the structure of naturally antibodies.

In the absence of the hand of man, the claimed antibodies are considered non-statutory subject matter (Diamond v. Chakrabarty, 206 U.S.P.Q.

193 (1980)). It should be noted that the mere purity of a naturally occurring product does not necessarily impart patentability (Ex parte Siddiqui, 156 U.S.P.Q. 426 (1966)). However, when purification results in a new utility, patentability is considered (Merck Co. v. Chase Chemical Co., 273 F.Supp 68 (1967), 155 USPQ 139, (District Court, New Jersey, 1967)).

Claims 6-17 recite antibodies, but do not recite that these antibodies are isolated or purified. The antibody as claimed are considered products that occur in nature and does not show the hand of man, and as such is non-statutory subject matter. It is suggested that the claims be amended to recite "an isolated CAB molecule" or "purified CAB molecule" to obviate this rejection.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Each of these claims cite "CAB", however this terminology is not art recognized. This terminology seems not to be of record in the specification. It is

Art Unit: 1643

not clear if this acronym denotes a "camel antibody" or "carcinoembryonic antigen binding". Applicants could obviate this instant rejection by listing the meaning or full terminology before the acronym in the initial citing of the first examined claim and/or independent claim in which it appears.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed

Art Unit: 1643

before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Begent et al./ U.S. Patent number US 7,232,888 B2 (filed July 1, 2003). Begent discloses sequence 6, an amino acid sequence modified from Applicants' amino acid sequence in SEQ ID NO: 1, wherein the modification is at least one position at position 184, see sequence alignment at end of instant rejection. Begent also discloses sequence 2 that is the same as Applicants' CAB molecule, SEQ ID NO: 1.

```
RESULT 10, rai database.
US-10-609-671-6
; Sequence 6, Application US/10609671
; Patent No. 7232888
; GENERAL INFORMATION:
; APPLICANT: Richard H.J. Begent
; APPLICANT: Kerry Ann Chester
; APPLICANT: Christilyn Graff
; APPLICANT: K. Dane Wittrup
; TITLE OF INVENTION: IMPROVED ANTIBODIES AGAINST TUMOR SURFACE ANTIGENS
; FILE REFERENCE: 117-455 / N.86090A PJC
; CURRENT APPLICATION NUMBER: US/10/609,671
; CURRENT FILING DATE: 2003-07-01
; PRIOR APPLICATION NUMBER: US 60/392354
; PRIOR FILING DATE: 2002-07-01
; NUMBER OF SEQ ID NOS: 25
; SOFTWARE: MS Word
; SEQ ID NO 6
; LENGTH: 285
; TYPE: PRT
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: humanized, affinity matured and stabilized murine antibody
; FEATURE:
; NAME/KEY: heavy chain CDR1
; LOCATION: (55)..(61)
; OTHER INFORMATION:
; FEATURE:
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Art Unit: 1643

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; NAME/KEY: heavy chain CDR2
; LOCATION: (81)..(86)
; OTHER INFORMATION:
; FEATURE:
; NAME/KEY: heavy chain CDR3
; LOCATION: (129)..(137)
; OTHER INFORMATION:
; FEATURE:
; NAME/KEY: light chain CDR1
; LOCATION: (190)..(194)
; OTHER INFORMATION:
; FEATURE:
; NAME/KEY: light chain CDR2
; LOCATION: (213)..(215)
; OTHER INFORMATION:
; FEATURE:
; NAME/KEY: light chain CDR3
; LOCATION: (254)..(259)
; OTHER INFORMATION:
US-10-609-671-6
```

```
Query Match          63.3%; Score 219; DB 3; Length 285;
Best Local Similarity 29.6%;
Matches 61; Conservative 0; Mismatches 145; Indels 0; Gaps 0;

Qy      26 GFNIKDSYMHXXXXXXXXXXXXXXXXXWIDPENGDEYAPKFQXXXXXXXXXXXXXXXXXXXXX 85
      ||||| |||||
Db      55 GFNIKDSYMHWLRQGPQQRLEWIGWIDPENGDEYAPKFQKGATFTTDTTSANTAYLGLSS 114

Qy      86 XXXXXXXXXXXXXGTPTGPYYFDYXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX 145
      ||||| |||||
Db      115 LRPEDTAVYYCNEGTPPTGPYYFDYWGQGTTLVTVSSGGGGSGGGSGGGGSENVLTQSPSS 174

Qy      146 XXXXXXXXXXXXXSASSSVSYMHXXXXXXXXXXXXXXXXXXSTSNLASXXXXXXXXXXXXXXXXX 205
      ||||| ||| |||||
Db      175 MSVSVGDRVTIACSASSVPYMHWLQKPGKSPKLLIYLTSNLASGVPSRFSGSGSGTDY 234

Qy      206 XXXXXXXXXXXXXXXXXXXXQQRSSYPLT 231
      ||||| |||||
Db      235 SLTISSVQPEDAATYYCQQRSSYPLT 260
```

RESULT 1 from 1.ra1 database.

US-10-609-671-2

```
; Sequence 2, Application US/10609671
; Patent No. 7232888
; GENERAL INFORMATION:
; APPLICANT: Richard H.J. Begent
; APPLICANT: Kerry Ann Chester
; APPLICANT: Christilyn Graff
; APPLICANT: K. Dane Witttrup
; TITLE OF INVENTION: IMPROVED ANTIBODIES AGAINST TUMOR SURFACE ANTIGENS
; FILE REFERENCE: 117-455 / N.86090A PJC
; CURRENT APPLICATION NUMBER: US/10/609,671
; CURRENT FILING DATE: 2003-07-01
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Art Unit: 1643

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; PRIOR APPLICATION NUMBER: US 60/392354
; PRIOR FILING DATE: 2002-07-01
; NUMBER OF SEQ ID NOS: 25
; SOFTWARE: MS Word
; SEQ ID NO 2
; LENGTH: 244
; TYPE: PRT
; ORGANISM: Mus musculus
US-10-609-671-2

```

```

Query Match          67.9%;  Score 235;  DB 3;  Length 244;
Best Local Similarity 30.6%;
Matches    63;  Conservative    0;  Mismatches  143;  Indels    0;  Gaps
0;

```

Qy 26 GFNIKDSYMHXXXXXXXXXXXXXXXXXWIDPENGDT EYAPKFQXXXXXXXXXXXXXXXXXXXXXXX 85
| | | | | | | | | | | | | | | | | | | |

Db 26 GFNIKDSYMHWLRQGPEQGLEWIGWIDPENGDT EYAPKFQGKATFTTDTSSNTAYLQLSS 85

Qy 86 XXXXXXXXXXXXXXXGTPTGPYYFDYXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
145

Db 86 LTSED TAVYYCNEG TPTGPYYFDYWGQGTTVTVSSGGGSGGGSGGGGSENVLTQSPA I
145

Qy 146 XXXXXXXXXXXXXXXXSSSSVSYMHXXXXXXXXXXXXXXXXXXSTSNLASXXXXXXXXXXXXXXXXXX
205

Db 146 MSASPGEKVTITCSASSSVSYMHWFQQKPGTSPKLWIYSTNLASGVPARFSGSGSGTSY
205

Qy 206 XXXXXXXXXXXXXXXXXXXXQQRSSYPLT 231

Db 206 SLTISRMEAEDAATYYCQQRSSSYPLT 231

9. Claim 7 is rejected under 35 U.S.C. 102(e) as being anticipated by Edwards et al./ U.S. Patent Application Publication number 2006/0141456 A1 (filed June 9, 2003). Edwards discloses sequence 2, which is the same as Applicants CAB molecule set forth in SEQ ID NO: 2, see sequence alignment at close of instant rejection.

```
RESULT 1, rapbm database.
US-10-514-516-2
; Sequence 2, Application US/10514516
; Publication No. US20060141456A1
; GENERAL INFORMATION:
; APPLICANT: Schellenberger, Volker
; APPLICANT: Tressler, Robert J.
; APPLICANT: Edwards, Cynthia
; APPLICANT: Fox, Judith Ann
; APPLICANT: Murray, Christopher J.
; TITLE OF INVENTION: Methods and Compositions for Milieu-Dependent Binding of a
; TITLE OF INVENTION: Targeted Agent to a Target
; FILE REFERENCE: GC768-2-US
; CURRENT APPLICATION NUMBER: US/10/514,516
; CURRENT FILING DATE: 2004-11-15
; PRIOR APPLICATION NUMBER: PCT/US2003/18200
; PRIOR FILING DATE: 2003-06-09
; PRIOR APPLICATION NUMBER: US 60/388,387
; PRIOR FILING DATE: 2002-06-12
; NUMBER OF SEQ ID NOS: 263
; SOFTWARE: PatentIn version 3.2
; SEQ ID NO 2
; LENGTH: 605
; TYPE: PRT
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: CAB1 scFv
US-10-514-516-2
```

```
Query Match          100.0%;  Score 3197;  DB 5;  Length 605;
Best Local Similarity 100.0%;
Matches 605;  Conservative 0;  Mismatches 0;  Indels 0;  Gaps 0;

Qy      1 QVKLQQSGAELVRSGTSVKLSCTASGFNIKDSYMHWLRQGPEQGLEWIGWIDPENGDEY 60
        |
Db      1 QVKLQQSGAELVRSGTSVKLSCTASGFNIKDSYMHWLRQGPEQGLEWIGWIDPENGDEY 60

Qy     61 APKFQGKATFTTDTSSNTAYLQLSSLTSEDVAVYYCNEGTPTGPYYFDYWGQGTTVTVSS 120
        |
Db     61 APKFQGKATFTTDTSSNTAYLQLSSLTSEDVAVYYCNEGTPTGPYYFDYWGQGTTVTVSS 120

Qy    121 GGGGSGGGGSGGGGSENVLTQSPAIMASAPGEKVTITCSASSSVSYMHWFQKPGTSPKL 180
        |
Db    121 GGGGSGGGGSGGGGSENVLTQSPAIMASAPGEKVTITCSASSSVSYMHWFQKPGTSPKL 180

Qy    181 WIYSTSNLASGVPARFSGSGSGTSYSLTISRMEADAATYYCQQRSSYPLTFGAGTKLEL 240
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Db      181  WIYSTSNLASGVPARFSGSGSGTSYSLTISRMEAEDAATYYCQQRSSYPLTFGAGTKLEL  240
Qy      241  KRAATPVSEKQLAEVVANTITPLMKAQSVPGMAVAVIYQGKPHYTFGKADIAANKPVTP  300
Db      241  KRAATPVSEKQLAEVVANTITPLMKAQSVPGMAVAVIYQGKPHYTFGKADIAANKPVTP  300
Qy      301  QTLFELGSISKFTFTGVLGGDAIARGEISLDDAVTRYWPQLTGKQWQGIRMLDLATYTAGG  360
Db      301  QTLFELGSISKFTFTGVLGGDAIARGEISLDDAVTRYWPQLTGKQWQGIRMLDLATYTAGG  360
Qy      361  LPLQVPDEVTDNASLLRFYQNWQPQWKPGTTRLYANASIGLFGALAVKPSGMPYEQAMTT  420
Db      361  LPLQVPDEVTDNASLLRFYQNWQPQWKPGTTRLYANASIGLFGALAVKPSGMPYEQAMTT  420
Qy      421  RVLKPLKLDHTWINVPKAEAAHYAWGYRDGKAVRVSPGMLDAQAYGVKTNVQDMANWVMA  480
Db      421  RVLKPLKLDHTWINVPKAEAAHYAWGYRDGKAVRVSPGMLDAQAYGVKTNVQDMANWVMA  480
Qy      481  NMAPENVADASLKQGIALAQSRWGRIGSMYQGLGWEMLNWPVEANTVVETSFGNVALAPL  540
Db      481  NMAPENVADASLKQGIALAQSRWGRIGSMYQGLGWEMLNWPVEANTVVETSFGNVALAPL  540
Qy      541  PVAEVNPPAPPVKASWVHKTGSTGGFGSYVAFIPEKQIGIVMLANTSYPNPARVEAAYHI  600
Db      541  PVAEVNPPAPPVKASWVHKTGSTGGFGSYVAFIPEKQIGIVMLANTSYPNPARVEAAYHI  600
Qy      601  LEALQ  605
Db      601  LEALQ  605
```

Conclusion

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana Harris Dent, Ph.D. whose telephone number is (571)272-0831. The Examiner works a **flexible schedule**, however she can generally be reached on 9 am to 6 pm, Monday through Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Misook Yu, Ph.D. can be reached on (571) 272-0839. The

Art Unit: 1643

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana Harris Dent, Ph.D.

14 December 2011

/Alana Harris Dent, Ph.D./

Primary Examiner, Art Unit 1643